

# (12) UK Patent Application (19) GB (11) 2 364 320 (13) A

(43) Date of A Publication 23.01.2002

(21) Application No 0016670.2

(22) Date of Filing 06.07.2000

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(51) INT CL<sup>7</sup>

A61M 15/00 , A61L 31/00

(52) UK CL (Edition T )

C3V VET

A5T TBD TBE

C3W W111 W113

U1S S1530 S1532

(56) Documents Cited

GB 2294506 A

GB 2272162 A

(58) Field of Search

UK CL (Edition R ) A5T TBD TBE , C3V VET

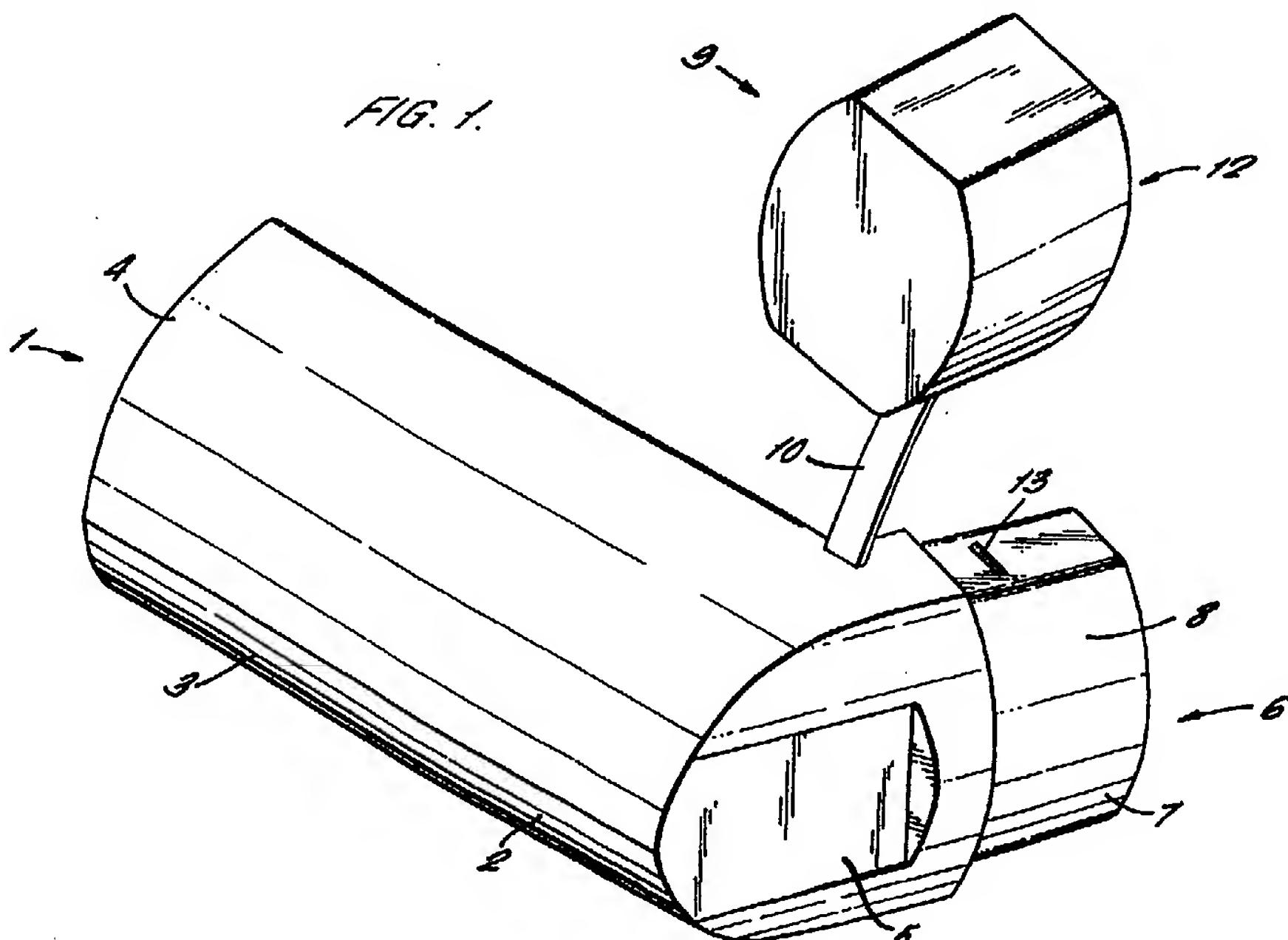
INT CL<sup>7</sup> A61L 31/00 , A61M 15/00

ONLINE; WPI, EPODOC, JAPIO

(54) Abstract Title

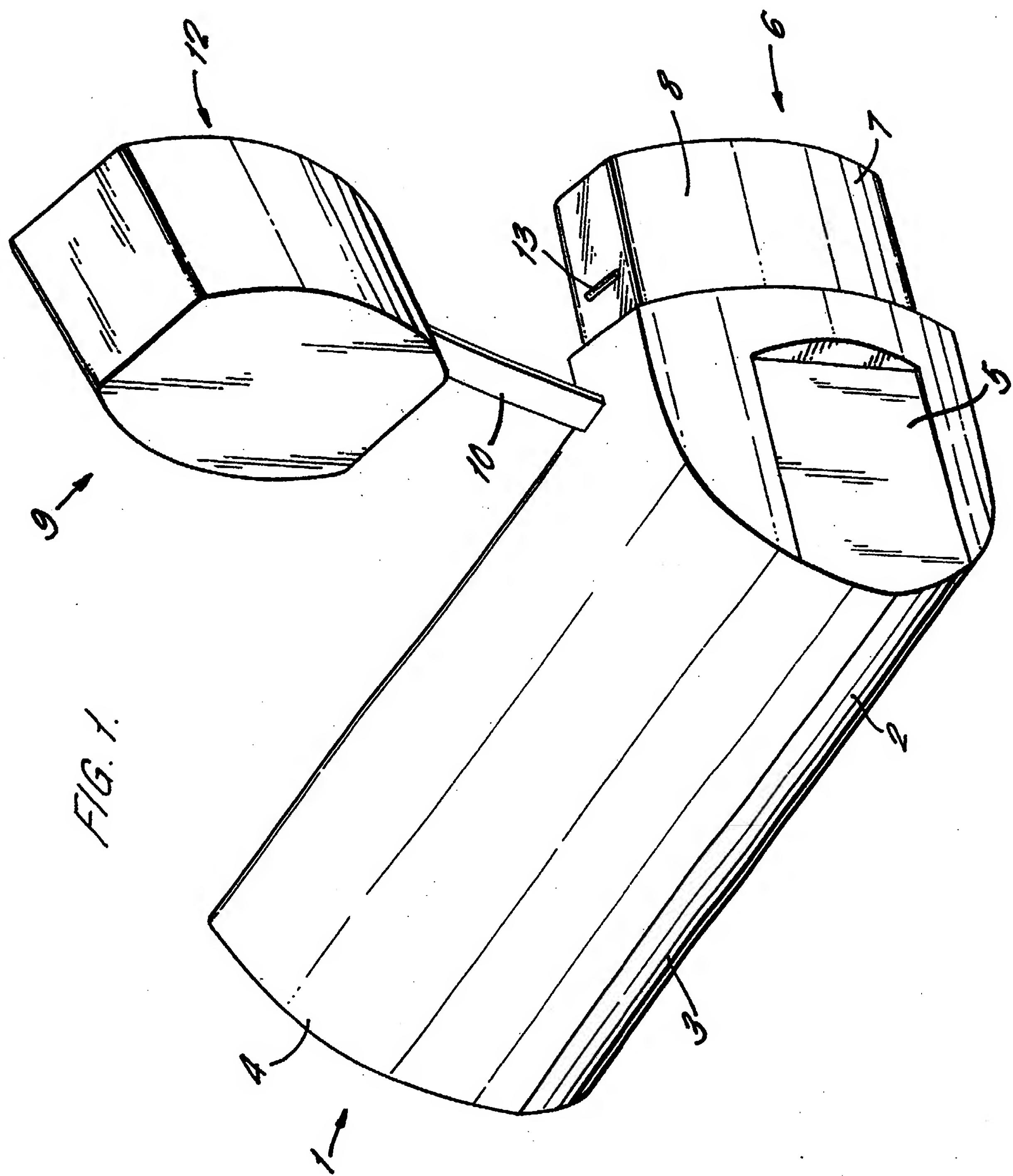
Dispensing apparatus

(57) Apparatus for dispensing a medicament comprising a housing 2 defining an outlet through which, in use, medicament is dispensed. A removable cap 9, engageable with the outlet to close it, is connected to the housing by a strap 10 which is formed from a thermoplastic elastomer having sufficient elasticity to accommodate the engagement and disengagement of the cap with the outlet. The cap, therefore, is still attached to the housing when disengaged from the outlet. The cap may also be formed from a thermoplastic elastomer. A pad (20, Fig. 3b) of thermoplastic elastomer may be formed at one end of the strap and be fixedly attached to the housing to form a non-slip surface. The cap, pad and strap may be formed as a unitary body. The housing and the unitary body comprising the strap, pad and cap may be formed in two separate moulding steps. The dispensing apparatus may be an aerosol spray, an inhalator, a nasal actuator, or a spacer.

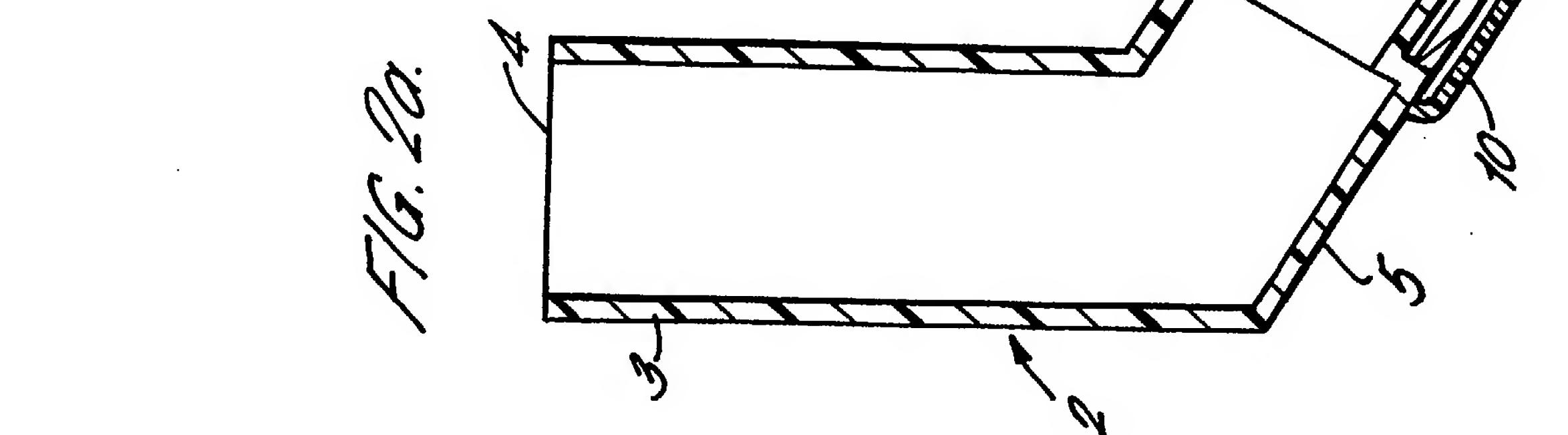
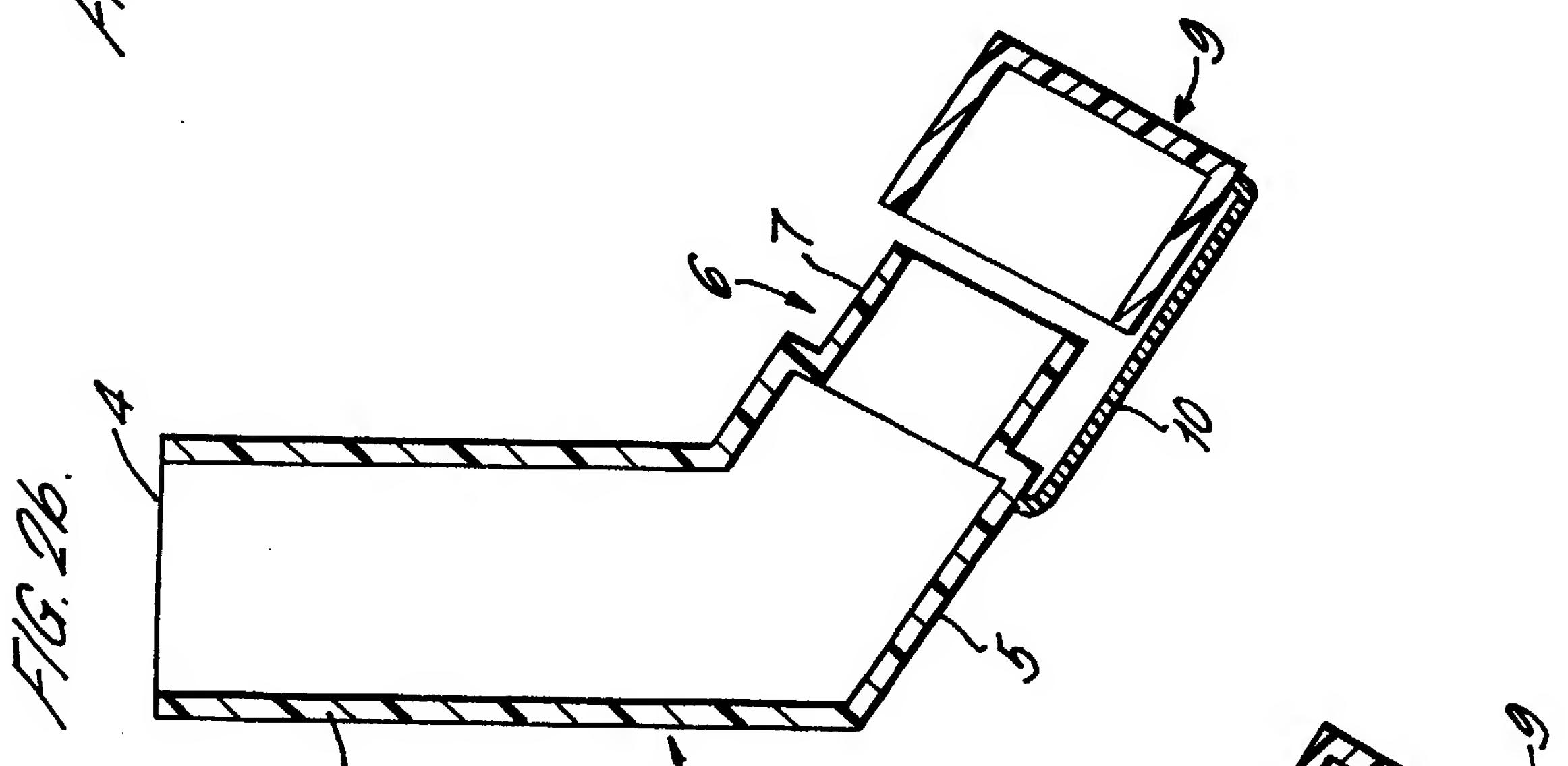
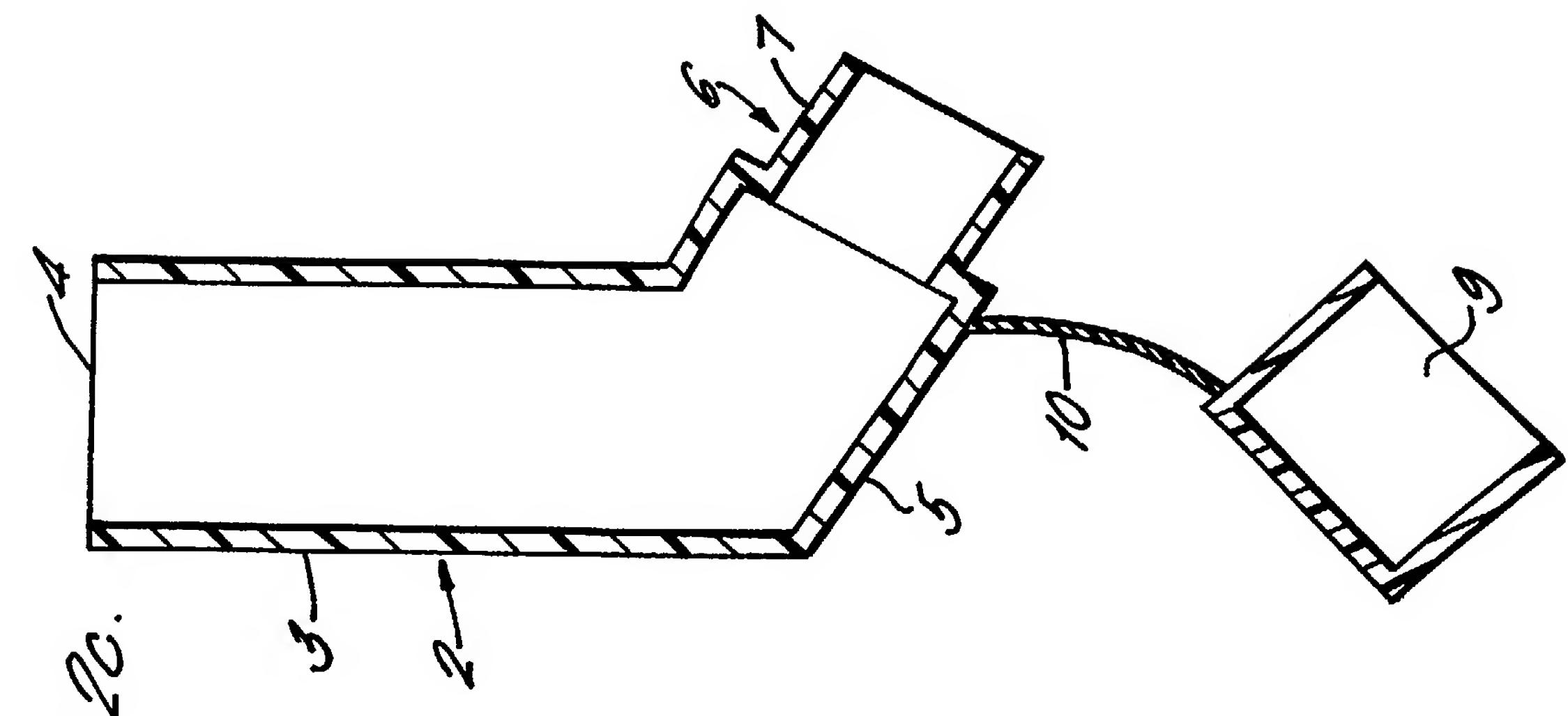


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FIG. 30.

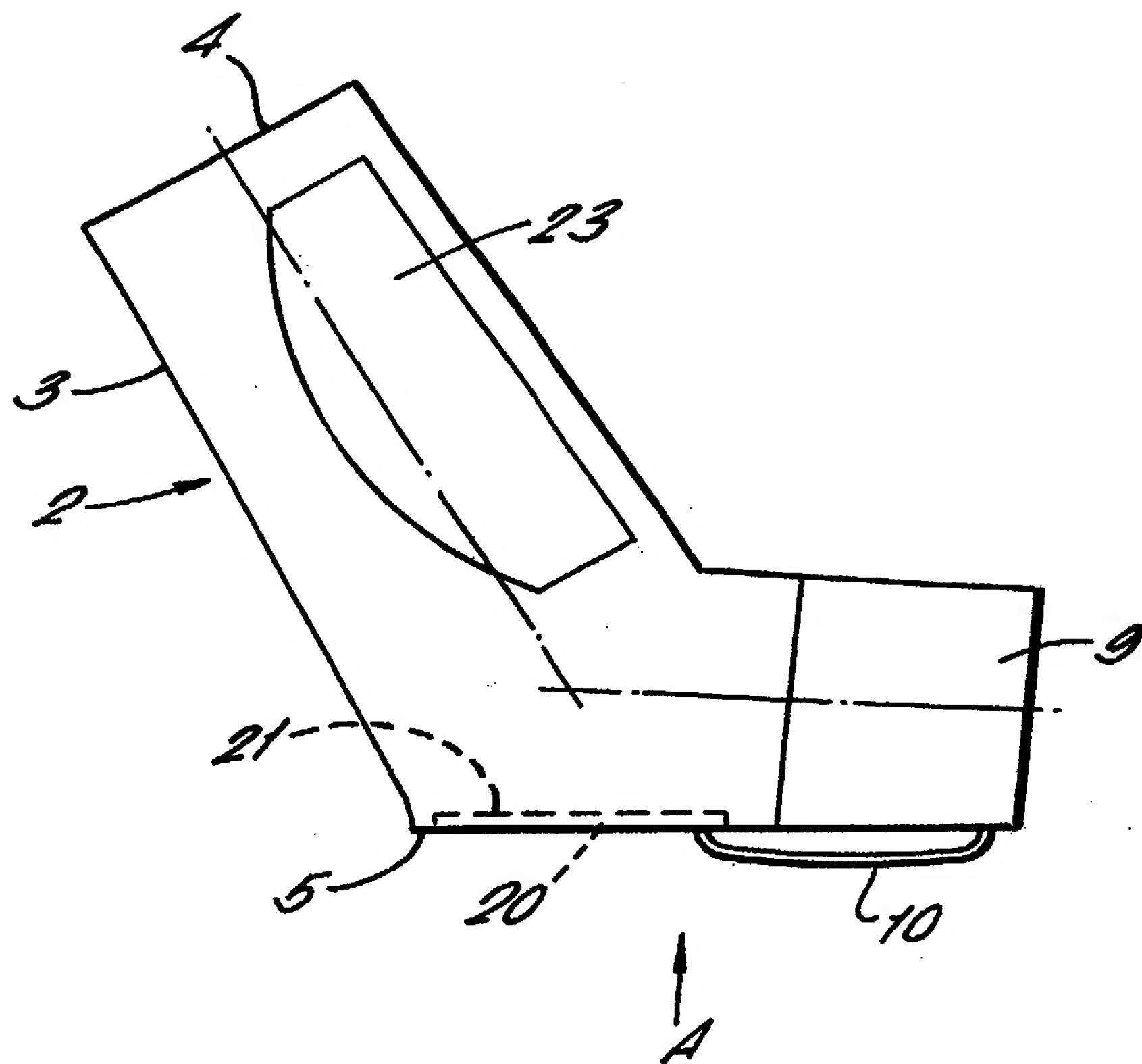
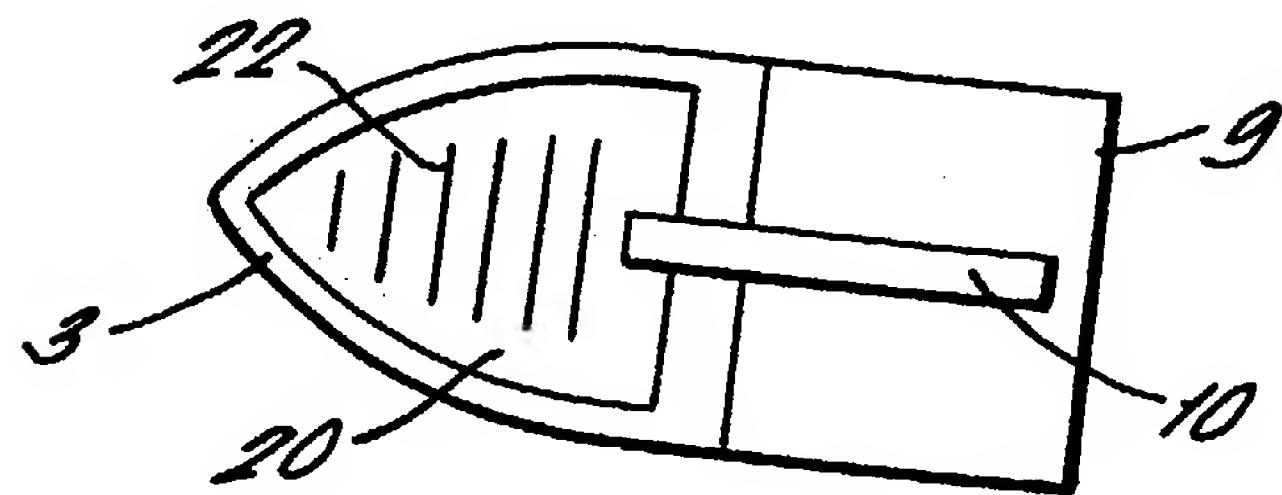
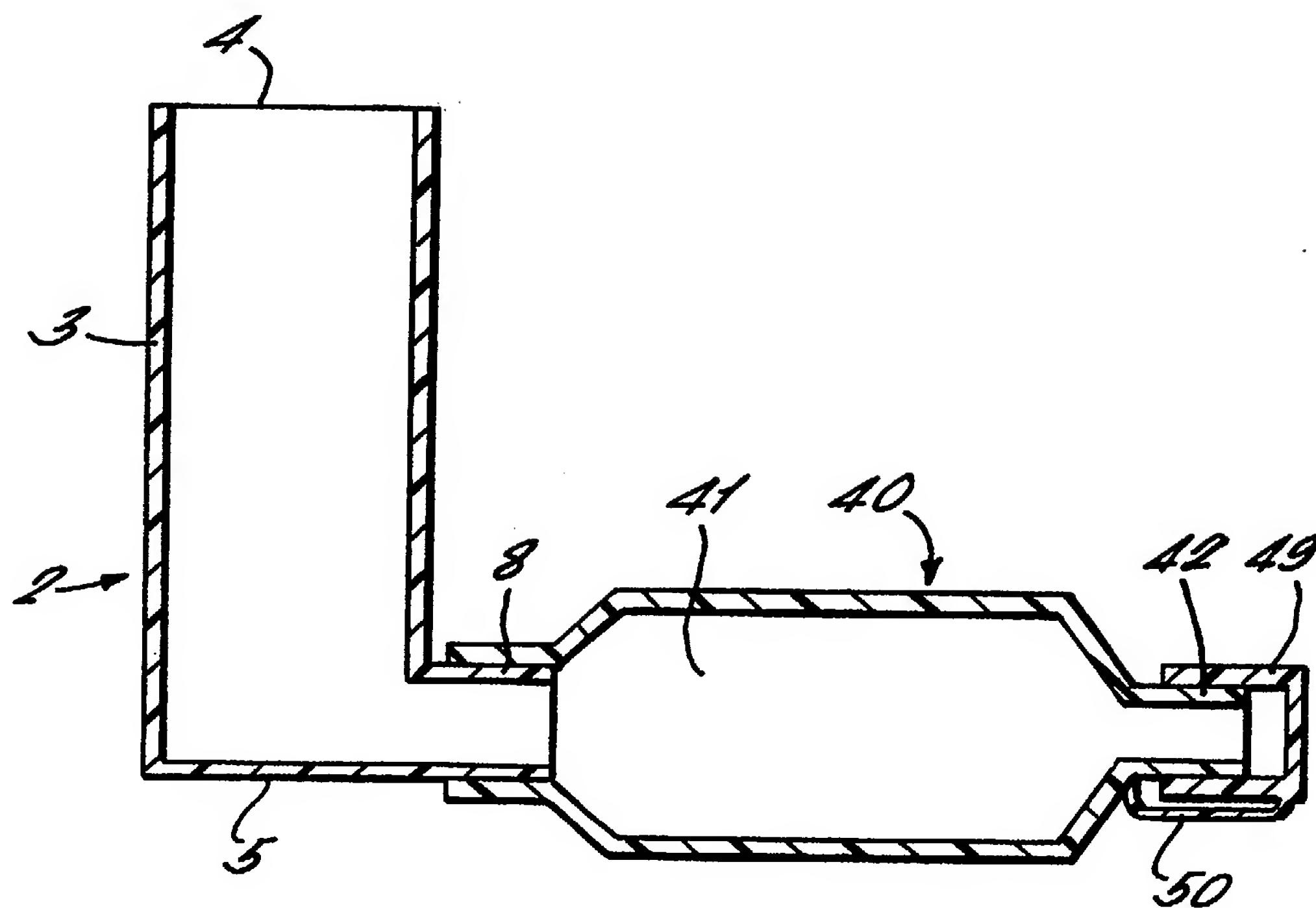


FIG. 3b.



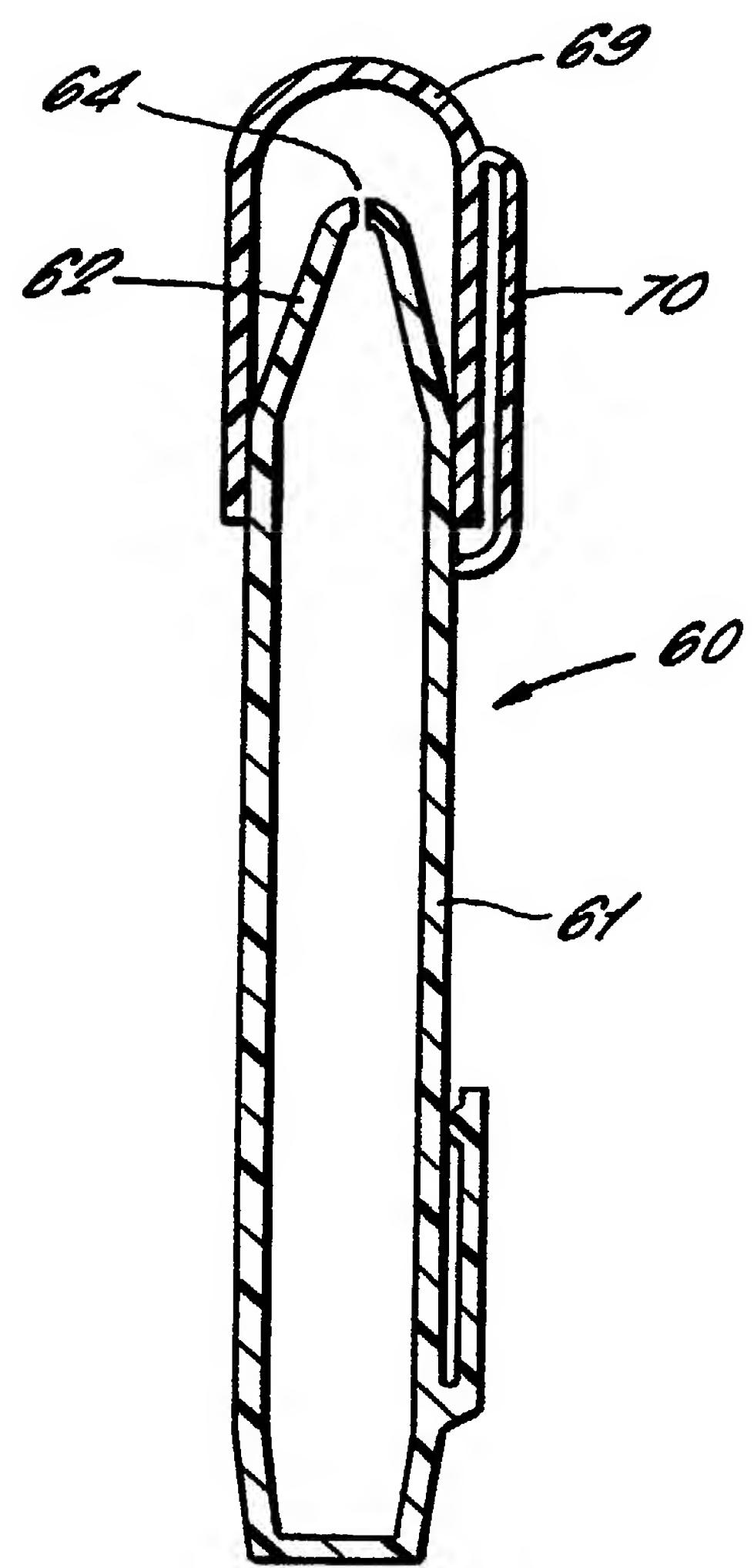
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FIG. 4.



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FIG. 5.



DISPENSING APPARATUS

This invention relates to apparatus for dispensing a medicament. In particular the invention 5 relates to apparatus such as oral and nasal actuators and spacers and an improved means of hygienically sealing such apparatus.

Oral actuators typically comprise a container in which the medicament is stored. Such containers 10 include pressurised dispensing containers, in which the medicament is stored in a liquid medium and dispensed using a volatile propellant, and frangibly-sealed containers, in which the medicament is stored as a dry powder and dispensed using an air stream. 15 Variants of such oral actuators include metered dose inhalers, pressurised metered dose inhalers, dry powder inhalers, breath actuated inhalers and breath co-ordinated inhalers.

Nasal actuators typically comprise a vial or 20 other container for storage of the medicament. Dispensation of the medicament via an outlet nozzle is achieved either by use of a volatile propellant or by a pressure being applied to the liquid medicament via a drive means.

25 Spacers are used in conjunction with another dispensing apparatus to provide a chamber or other generally enclosed space in which the velocity of dispensed medicament particles may be slowed before they are administered to a user, either orally or 30 nasally.

A common feature of all oral and nasal actuators and spacers is that an outlet is provided through 35 which the medicament is dispensed. The outlet may be a mouthpiece in the case of oral actuators and spacers or a generally conically-shaped tip in the case of a nasal actuator. The mouthpiece or tip are contacted by the user during use. Therefore it is important that

the surfaces of the mouthpiece or tip are kept free from dirt, dust and other contaminants. In addition it is advantageous to provide a means for sealing the outlet of the apparatus to prevent the ingress of 5 dirt, dust or other contaminants into the body of the apparatus.

It is known to provide a cap to close the outlet of such dispensing apparatus. It has been proposed for such caps to be retained captive relative to a 10 housing of the apparatus by means of a flexible strap secured at one end to the housing in order to prevent loss of the cap and to prevent accidental swallowing of the cap, the strap being of sufficient length to allow the cap to be moved into close proximity with 15 that portion of the mouthpiece or tip which is contacted in use, and the cap being received as a snap fit onto the housing so as to close the outlet.

A disadvantage of such an arrangement is that the surface area of the portion likely to be coming into 20 contact with the user's mouth or nose is only partially overlaid by most known caps when secured to the mouthpiece or tip thereby leaving the apparatus susceptible to contamination by handling and storage prior to use.

25 GB 2272162A describes an oral actuator comprising a removable cap engagable with a mouthpiece and a strap connecting the cap to a tubular body of a housing. The strap is of sufficient length to allow the cap to be moved axially relative to the mouthpiece 30 to allow for engagement and removal of the cap from the mouthpiece. In the engaged position the strap, being relatively stiff, bows into an arcuate shape away from the housing. This tends to make the dispensing apparatus more bulky, especially for the 35 purposes of storage. Also the strap is easily caught on objects leading to the potential accidental removal of the cap from the mouthpiece. The strap is also not

aesthetically pleasing.

GB 2294506A describes one solution to the disadvantages inherent in the apparatus of GB 2272162A. The strap comprises a web of plastics material having formed therein a plurality of transverse grooves defining fold lines about which the web is foldable in bellows formation to accommodate extension and retraction of the strap during the axial movement of the cap. A problem with this solution is that the relatively thin hinge is prone to fatigue failure after repeated use. A thicker hinge cannot be utilised since the cap would then spring back so as to impede the user's access to the mouthpiece. In addition the webbed strap is relatively expensive and difficult to mould. Also, a disadvantage common to such caps is that the relatively 'hard' nature of the material of the cap is capable of scratching the face of the user during use.

According to the present invention there is disclosed apparatus for dispensing a medicament, comprising a housing defining an outlet through which, in use, medicament is dispensed, a removable cap engageable with the outlet to close the outlet, and a strap connecting the cap to the housing whereby the cap is still attached to the housing when disengaged from the outlet, wherein the strap is formed from a thermoplastic elastomer having sufficient elasticity to accommodate the engagement and disengagement of the cap with the outlet.

Preferably, the length of the strap is such that the strap lies in close proximity with the housing when the cap is engaged with the outlet.

Preferably the cap is formed from a thermoplastic elastomer.

Preferably, the cap and strap are formed as a unitary body.

Preferably a pad of thermoplastic elastomer

material is formed at one end of the strap, the pad being fixedly attached to the housing to form a non-slip surface. Optionally the pad, strap and cap are formed as a unitary body.

5 Preferably, one of the housing or the unitary body comprising the pad, strap and cap is formed in a first moulding step and the other of the housing or the unitary body comprising the pad, strap and cap is formed in a second moulding step.

10 Optionally one or more portions of the housing are coated with thermoplastic elastomer to form a non-slip surface.

15 In one embodiment movement of the cap into and out of engagement with the outlet is accompanied by co-axial relative movement of the cap and the outlet.

In one embodiment the apparatus comprises a pressurised dispensing container operable to dispense an aerosol spray.

20 In another embodiment the apparatus comprises an inhalator operable to dispense a powdered medicament.

In another embodiment the apparatus comprises a nasal actuator.

In another embodiment the apparatus is a spacer.

25 Preferably the thermoplastic elastomer is one of Santoprene, Pebax, Vitaprene or Hytrel or the like

Preferred embodiments of the present invention will now be described by way of example only and with reference to the accompanying drawings in which:-

30 Figure 1 is a perspective view of a first embodiment of apparatus according to the present invention having an integrally formed strap attached to a side wall and with the cap disengaged from the mouthpiece;

35 Figure 2a is a cross-sectional schematic view of a second embodiment of apparatus according to the present invention having an integrally formed strap

attached to an end wall and the cap being in the engaged position on the mouthpiece;

5 Figure 2b is a cross-sectional schematic view of the apparatus of Figure 2a showing the cap in co-axial alignment with the mouthpiece immediately prior to movement of the cap into the engaged position on the mouthpiece;

10 Figure 2c is a cross-sectional schematic view of the apparatus of Figure 2a showing the cap in an unengaged position, for example, during actuation of the apparatus;

15 Figure 3a is a side view of a third embodiment of dispensing apparatus according to the present invention showing the cap in the engaged position on the mouthpiece;

Figure 3b is a view of the apparatus of Figure 3a in the direction of arrow A in Figure 3a;

20 Figure 4 is a schematic side view of a forth embodiment of dispensing apparatus according to the present invention showing the cap in the engaged position on the mouthpiece; and

25 Figure 5 is a schematic side view of a fifth embodiment of dispensing apparatus according to the present invention showing the cap in the engaged position on the actuator tip.

30 Figure 1 shows a first embodiment of the present invention, whilst Figures 2a to 2c show a second embodiment of the present invention. In both embodiments the apparatus 1 comprises a housing 2 of plastics material, such as polypropylene, consisting of a tubular body 3 having a tubular side wall and an open end 4. The body 3 is closed at its opposite end by an end wall 5 and a tubular mouthpiece 6 projects laterally of the body at a location immediately adjacent the end wall 5. The mouthpiece 6 has a tubular lip portion 7 having an external surface 8

which in use is presented to the lips of a user wishing to inhale orally via the mouthpiece an aerosol spray generated from a pressurised dispensing container (not shown) normally received within the 5 body 3.

The apparatus 1 further comprises a cap 9 which is connected to the body 3 by a strap 10 formed of a thermoplastic elastomer material such as Santoprene, Pebax, Vitaprene, Hytrel or the like. The strap 10 is 10 joined to the cap 9 and housing 2 by mechanical fasteners, glue, heated or ultrasonic welds, or a combination of these means.

In the first embodiment, shown in Figure 1, the cap 9 is attached to a side of the tubular body 3. In 15 the second embodiment, shown in Figures 2a to 2c, the strap 10 is attached to the end wall 5. In other respects the first and second embodiments are identical. As such, the engagement and disengagement of the cap will now be described with reference to the 20 second embodiment only.

Advantageously, the inherent elasticity of the thermoplastic elastomer material allows the strap 10 to stretch and extend in length when the cap 9 is pulled in a direction away from the tubular body 3.

The cap 9 is a sliding fit onto the lip portion 7 such that an internal surface 12 of the cap totally overlays the external surface 8 of the lip portion when the cap is moved into an engaged position as 25 shown in Figure 2a in which it is engaged with the mouthpiece 6.

The lip portion 7 and the cap 9 are provided with co-operating snap fit connectors which include a detent 13 projecting from the lip portion in co-operating relationship with a groove (not shown) 30 formed in the internal surface 12 of the cap 9.

As shown in Figure 2c, the cap is movable when disengaged from the mouthpiece 8 into a position in

which it lies at a location which is offset from the axial extent of the body 3 and from the axial extent of the mouthpiece 6 by a distance determined by the length of the strap 10. Due to the relative 5 flexibility of the strap 10 the cap tends to 'fall away' from the mouthpiece 6 when it is disengaged which greatly improves access to the mouthpiece 6.

In this position, the user is able to grip the housing without interference from the presence of the 10 cap 9 and strap 10, the user typically resting a thumb against the end wall 5 and an index finger around the barrel shaped body 3.

In order to move the cap 9 from this position of 15 Figure 2c into the engaged position of Figure 2a it is necessary to move the cap 9 away from the body 3 into co-axial alignment with the mouthpiece 6 at a position in which the cap 9 extends beyond the axial extent of the lip portion 7, as shown in Figure 2b. During this movement the strap 10 is stretched. The maximum 20 extended length of the strap 10 must correspond at least to this configuration. Movement of the cap into the engaged position then proceeds by pushing the cap 9 towards the body 3 in sliding relationship relative to the lip portion 7 until the detent 13 effects a 25 snap fit connection and the cap rests in the fully engaged position shown in Figure 2a in which the entire external surface 8 of the lip portion 7 is overlaid.

In the engaged position of Figure 2a it is seen 30 that the strap 10 has elastically recovered to its original, unstretched length, such that the strap 10 is held close to the body 3 and does not extend away from the body 3 in a loop formation. As a result the risk of catching the strap 10 on an object and 35 accidentally dislodging the cap 10 is greatly reduced. Also the overall dimensions of the apparatus in the storage condition are reduced.

Cap 9 may be formed from a plastics material such as polypropylene. Advantageously, according to a further aspect of the present invention, the cap 9 may also be formed from a thermoplastic elastomer. The 5 cap 9 and strap 10 may then be formed as a unitary body by means of a moulding process. The inherent flexibility of the thermoplastic elastomer allows the cap 9 to be distorted or crushed and yet return to its original shape. This is advantageous in that it both 10 simplifies removal and engagement of the cap 9 with the mouthpiece 8 as the cap 9 can distort somewhat but also in that the cap does not risk scratching the face of the user during use.

Figures 3a and 3b show a third embodiment of the 15 present invention. Similar components to those shown in the first and second embodiments have been referenced with the same reference numerals and will not be described here in any more detail. Strap 10 is connected to the cap 9 as in the second embodiment. 20 At the other end of the strap 9 is formed a pad 20 of a thermoplastic elastomer material, such as Santoprene Pebax, Vitaprene, Hytrel or the like. The pad 20 may be connected to the strap 10 by any of the methods described above in connection with the first and 25 second embodiments. However, preferably the strap 10 and pad 20 are formed as a unitary body by a moulding process. In the case where the strap 10, cap 9 and pad 20 are all formed of a thermoplastic elastomer, preferably they are formed as a single unitary body by 30 means of a moulding process.

The pad 20 serves as a "key" which is received in a recessed "key-way" 21 in the end wall 5 of the tubular body 3. The pad 20 is fixedly attached to the recessed "key-way" 21 by any of the methods described 35 above in the first embodiment, e.g. welding, mechanical fasteners, glue etc. The "key" and "key-way" arrangement provides an improved connection

between the thermoplastic elastomer and the polypropylene materials. Alternatively the pad 20 may be simply bonded to the surface of the end wall 5 without the use of a key-way.

5 Advantageously, where the cap 9, strap 10 and pad 20 are all formed from a thermoplastic elastomer the apparatus may be formed as a two-step moulding. In the first step the housing 2 is moulded from a polypropylene or similar material and in the second 10 step the cap 9, strap 10 and pad 20 are moulded from a thermoplastic elastomer directly into position on the housing 2, with the pad 20 being retained on the housing 2 by a mixture of physical and chemical bonding. Preferably both steps of the moulding 15 process are carried out in the same mould tool. Alternatively, the moulded housing 2 may be moved to a different mould tool for the second step. The two mould steps could be reversed in order.

20 Optionally the housing 2 is provided with a re-entrant feature through which the pad 20 is moulded to provided for improved attachment of the pad 20 to the housing 2.

25 Preferably the pad 20 is provided with ridges 22 or other surface protrusions or indentations. These serve to improve the grip of the user's finger or thumb when holding the apparatus.

30 In a further aspect of the present invention, one or more portions 23 of the tubular body 3 are provided with a coating of a thermoplastic elastomer, as shown in Figure 3a. The thermoplastic elastomer coated portions 23 provide for an improved grip of the tubular body 3.

35 Figure 4 shows a fourth embodiment of the present invention comprising a spacer 40 attached to an oral actuator of the type shown in Figures 1 to 3b.

The spacer 40 attaches to the mouthpiece 8 of the oral actuator and provides a chamber 41 in which the

dispensed medicament particles slow before inhalation. A mouthpiece 42 generally opposite the mouthpiece 8 of the oral actuator is provided with a cap 49 which is attached to the spacer body by means of a strap 50.

5 The structure, materials and operation of the strap and cap arrangement are the same as for the second and third embodiments and will not be described further. Of course the strap and cap arrangement of the present invention may be applied to other types of spacer or

10 where the spacer is attached to other types of actuator.

Figure 5 shows a fifth embodiment of the present invention comprising a nasal actuator 60 having a body 61, tip 62 and cap 69. The tip 62 defines an outlet 64 through which medicament is dispensed. The nasal actuator 60 is provided with a cap 69 which is attached to the spacer body by means of a strap 70. The structure, materials and operation of the strap and cap arrangement are the same as for the second, third and fourth embodiments and will not be described further.

CLAIMS:-

1. Apparatus for dispensing a medicament, comprising a housing defining an outlet through which, in use, medicament is dispensed, a removable cap engageable with the outlet to close the outlet, and a strap connecting the cap to the housing whereby the cap is still attached to the housing when disengaged from the outlet, wherein the strap is formed from a thermoplastic elastomer having sufficient elasticity to accommodate the engagement and disengagement of the cap with the outlet.  
5
2. Apparatus as claimed in claim 1 wherein the length of the strap is such that the strap lies in close proximity with the housing when the cap is engaged with the outlet.  
15
3. Apparatus as claimed in claim 1 or claim 2 wherein the cap is formed from a thermoplastic elastomer.  
20
4. Apparatus as claimed in claim 3 wherein the cap and strap are formed as a unitary body.  
25
5. Apparatus as claimed in any preceding claim wherein a pad of thermoplastic elastomer material is formed at one end of the strap, the pad being fixedly attached to the housing to form a non-slip surface.  
30
6. Apparatus as claimed in claim 5 wherein the pad, strap and cap are formed as a unitary body.  
35
7. Apparatus as claimed in claim 6 wherein one of the housing or the unitary body comprising the pad, strap and cap is formed in a first moulding step and the other of the housing or the unitary body

comprising the pad, strap and cap is formed in a second moulding step.

8. Apparatus as claimed in any preceding claim  
5 wherein one or more portions of the housing are coated with thermoplastic elastomer to form a non-slip surface.

9. Apparatus as claimed in any preceding claim  
10 wherein movement of the cap into and out of engagement with the outlet is accompanied by co-axial relative movement of the cap and the outlet.

10. Apparatus as claimed in any preceding claim  
15 wherein the apparatus comprises a pressurised dispensing container operable to dispense an aerosol spray.

11. Apparatus as claimed in any of claims 1 to 9  
20 wherein the apparatus comprises an inhalator operable to dispense a powdered medicament.

12. Apparatus as claimed in any of claims 1 to 9  
25 wherein the apparatus comprises a nasal actuator.

13. Apparatus as claimed in any of claims 1 to 9  
wherein the apparatus is a spacer.

14. Apparatus as claimed in any preceding claim  
30 wherein the thermoplastic elastomer is one of Santoprene, Pebax, Vitaprene or Hytrel or the like.

15. Apparatus substantially as hereinbefore described  
35 with reference to and as shown in the accompanying drawings.

**Amendments to the claims have been filed as follows**

1. Apparatus for dispensing a medicament, comprising a housing defining an outlet through which, in use, medicament is dispensed, a removable cap engageable with the outlet to close the outlet, and a strap connecting the cap to the housing whereby the cap is still attached to the housing when disengaged from the outlet, wherein the strap is formed from a thermoplastic elastomer having sufficient elasticity to accommodate the engagement and disengagement of the cap with the outlet.
2. Apparatus as claimed in claim 1 wherein the length of the strap is such that the strap lies in close proximity with the housing when the cap is engaged with the outlet.
3. Apparatus as claimed in claim 1 or claim 2 wherein the cap is formed from a thermoplastic elastomer.
4. Apparatus as claimed in claim 3 wherein the cap and strap are formed as a unitary body.
5. Apparatus as claimed in any preceding claim wherein a pad of thermoplastic elastomer material is formed at one end of the strap, the pad being fixedly attached to the housing to form a non-slip surface.
6. Apparatus as claimed in claim 5 wherein the pad, strap and cap are formed as a unitary body.
7. Apparatus as claimed in claim 6 wherein one of the housing or the unitary body comprising the pad, strap and cap is formed in a first moulding step and the other of the housing or the unitary body

comprising the pad, strap and cap is formed in a second moulding step.

8. Apparatus as claimed in any preceding claim  
5 wherein one or more portions of the housing are coated with thermoplastic elastomer to form a non-slip surface.

9. Apparatus as claimed in any preceding claim  
10 wherein movement of the cap into and out of engagement with the outlet is accompanied by co-axial relative movement of the cap and the outlet.

10. Apparatus as claimed in any preceding claim  
15 wherein the apparatus comprises a pressurised dispensing container operable to dispense an aerosol spray.

11. Apparatus as claimed in any of claims 1 to 9  
20 wherein the apparatus comprises an inhalator operable to dispense a powdered medicament.

12. Apparatus as claimed in any of claims 1 to 9  
wherein the apparatus comprises a nasal actuator.  
25

13. Apparatus as claimed in any of claims 1 to 9  
wherein the apparatus is a spacer.

14. Apparatus substantially as hereinbefore described  
30 with reference to and as shown in the accompanying drawings.



Application No: GB 0016670.2  
Claims searched: 1-15

15

Examiner: Chris Archer  
Date of search: 9 November 2000

## Patents Act 1977 Search Report under Section 17

### Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.R): A5T (TBE, TBD) C3V (VET)

Int Cl (Ed.7): A61M (15/00) A61L (31/00)

Other: ONLINE: WPI, EPODOC, JAPIO

### Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
A	GB 2294506 A (BESPAK)	
A	GB 2272162 A (YERBURY)	

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.